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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/081,457   | 02/21/2002  | Anne M. Pianca       | 98PI021US08             | 3029             |
| 36802  | 7590        | 04/08/2005           | EXAMINER                |                  |
| PACESETTER, INC.<br>15900 VALLEY VIEW COURT<br>SYLMAR, CA 91392-9221 |             |                      | EVANISKO, GEORGE ROBERT |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 3762                    |                  |
| DATE MAILED: 04/08/2005  |             |                      |                         |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                     |  |
|------------------------------|-------------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>        | <b>Applicant(s)</b> |  |
|                              | 10/081,457                    | PIANCA ET AL.       |  |
|                              | Examiner<br>George R Evanisko | Art Unit<br>3762    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 August 2004.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-17 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

The 1.131 affidavits filed on 8/30/04 under 37 CFR 1.131 have been considered but are ineffective to overcome the Hsu et al reference.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Hsu reference to either a constructive reduction to practice or an actual reduction to practice. Exhibit B does not contain a date (See MPEP 715.07, “the actual dates of acts relied on to establish diligence must be provided”) to show diligence. In addition, there are non-diligent time periods from: Exhibit B (dated “prior to March 19, 1998”) to Exhibit C, dated June 27, 1997; from Exhibit C to Exhibit D of receiving a draft application on July 1, 1998--a period of over one year; Exhibit D To Exhibit E, dated October 23, 1998; and Exhibit E to the filing of the application, dated November 20, 1998.

Since no reduction to practice has been shown, the Examiner has concluded that the 1.131 declarations are used to show “conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice)” to show facts sufficient to establish prior invention of the claimed subject matter. The critical period in which diligence must be shown begins just prior to the effective date of the reference and ends with the filing date of the application (MPEP 715.07(a)). Exhibit B or any other exhibit does not contain a date to show diligence just prior to the effective date of the reference. In addition, there are numerous time periods between exhibits where diligence has not been shown. For example, between Exhibit C and Exhibit D a period of one year has elapsed (See MPEP 2138.06 regarding diligence required

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in preparing and filing patent application). In addition, after the draft was received by the Legal Department (Exhibit D) no diligence is shown for the three and a half month period until receiving the revised draft. Finally, after the revised draft is received by the Legal Department, no diligence is shown for the period of approximately a month until the application was filed. (See MPEP 2138.06--“An applicant must account for the entire period during which diligence is required” and “A 2-day period lacking activity has been held to be fatal”.)

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 6, 9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Hsu et al (6430449). For claim 4, Hsu et al will meet the intended use recitations presented in the claim since the stylet can be moved anywhere along the bends to cant the tip toward the patients wall (the “steerable canted end” is used in claim 2 when the stylet is partially withdrawn).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hsu et al. Hsu shows in figure 5 the lead having non-helical bends comprising two-sides forming an angle in the range of about 45 degrees, which is in the range of 30-150 degrees.

In the alternative, Hsu discloses the claimed invention except for the bends having an angle of 30-150 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Hsu, with the bends having an angle of 30-150 degrees since it was known in the art that heart leads having an anchor use anchor bends having an angle of 30-150 degrees to allow the lead to easily anchor in the heart and provide good stability to prevent movement of the lead.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al as applied to claims 6 and 1 above.

Hsu discloses the claimed invention except for the humps being in different geometric planes. It would have been an obvious matter of design choice to one skilled in the art to modify

the anchoring lead as taught by Hsu with the humps in the anchor being located in different geometric planes, since applicant has not disclosed that providing the humps in different geometric planes provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any location of the humps, such as the humps being located in the same plane as taught by Hsu to anchor the lead in the coronary sinus and provide contact with the wall only along the humps.

Claims 3, 7, 8, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu as applied to claims 2, 6, and 1 above. For claim 8, Hsu states that the bends are located 8-11 mm from each other.

Hsu discloses the claimed invention except for the lead having a distal opening to receive a guidewire, the stylet having a tapered portion, the first bend located in the range of 0.15-0.7 inches from the distal end, and the lead having a textured region of ePTFE or porous material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical electrical lead as taught by Hsu with the lead having a distal opening to receive a guidewire, the stylet having a tapered portion, and the lead having a textured region of ePTFE or porous material (such as silicone rubber, polyurethane, or ceramic) since it was known in the art that medical electrical leads have a distal opening to receive a guidewire to allow the lead to be positioned in the body, that leads use a stylet with a tapered portion to allow the stylet to fit in the narrow distal end of the lead and to position the lead, and that leads have a textured region of ePTFE or porous material to allow the lead to anchor in the body.

In addition, it would have been an obvious matter of design choice to one skilled in the art to modify the medical electrical lead as taught by Hsu to include ePTFE as the textured

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region and the first bend being located 0.15-0.7 inches from the distal end, since applicant has not disclosed that ePTFE and the first bend being located 0.15-0.7 inches from the distal end provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any biocompatible textured material or any location of the bends, such as silicone rubber, polyurethane or ceramic for allowing the lead to anchor in the body as taught by Hsu in view of one having ordinary skill in the art for allowing the lead to anchor in the coronary sinus or such as the S-shaped or zig-zag shaped lead location of the bends as taught by Hsu to allow the lead to anchor in the coronary sinus and provide electrodes for electrical contact with the heart chambers.

***Response to Arguments***

Applicant's arguments filed 8/30/04 have been fully considered but they are not persuasive.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko  
Primary Examiner  
Art Unit 3762

4/6/5

GRE  
April 6, 2005